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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,419	10/27/2000	Gabriel Vogeli	28341/6276NCP	5650

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EXAMINER
ULM, JOHN D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/698,419	Applicant(s) Vogeli et al.
	Examiner John Ulm	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 29, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *45-48* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *45-48* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 45 to 48 are pending in the instant application. Claims 45 to 47 have been amended and claims 1 to 44 and 49 to 77 have been canceled as requested by Applicant in Paper Number 12, filed 29 November of 2002.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4) Claims 45 to 48 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper Number 10.

Applicant has traversed this rejection on the premise that membership in the G protein-coupled receptor family is, alone, sufficient to establish a utility for a specific protein and, therefore, the claimed assay. Applicant asserts that a protein of the instant invention belongs to a family of proteins of which some members are the targets of "nearly" 350 therapeutic agents currently on the market. This number is actually higher since a number of agents such as antidepressants and hypertension medications were being employed clinically before their site of action was known. However, each clinical agent which has been developed by measuring its

interaction with a specific G protein-coupled receptor was evaluated against a receptor whose native ligand and physiological function were known, such as the adrenergic receptors, the dopamine receptors and the serotonin receptors There are also numerous G protein-coupled receptors such as odorant receptors and calcium sensing receptors which do not appear to mediate any clinically significant process. More importantly, an artisan knew, before they employed a specific G protein-coupled receptor to identify clinically useful compounds, which physiological process or processes they wished to manipulate and that the protein employed in their assay had an influence of that process. Even if one identifies an agonist or antagonist for a receptor of the instant invention by employing the claimed method, this information is useless since one has no idea of what clinical effect the administration of that agonist or antagonist to an individual would have.

Applicant's reference to Patent Number 6,071,722 as establishing a patentable utility for the claimed process is not persuasive because each application is examined on its own merits. In the decision of *In re Hutchison*, 69 USPQ 138 (CCPA, 1946), the court held that

> "We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the six article claims on appeal were properly rejected below, and this we pass upon without further reference to, and without comparing them with, the claims in the patent or the claims which stand allowed in this application."

In essence, the position in the instant application that each application is examined on its own merits can be found in the judicial precedent cited above. The rejections in the instant application

will only be withdrawn if they are shown to be legally or factually unsound. The fact that a patent may have issued in error does not relieve the USPTO from the responsibility of preventing the reoccurrence of such errors wherever possible.

Applicant urges that the claimed assay has a specific utility because it only relates to the protein employed therein. Whereas it is certainly a specific utility, it is not a substantial or practical utility because the instant specification fails to disclose the significance of the binding activity detected by the claimed assay. Any protein can be employed to identify compounds which bind thereto but this information is of no practical utility unless one can attribute some specific desirable or undesirable property to a compound based upon that compound's ability to bind to the protein in question. Since the instant specification has not shown that the inhibition or activation of the protein employed in the claimed assay effects a specific physiological process, the identification of agonists or antagonists to that protein is an investigative activity of no practical value.

Applicant asserts that the protein of the instant invention is associated with schizophrenia because the gene encoding it maps to position 7q21, which is allegedly linked to schizophrenia, and because it is expressed in certain regions of the rat brain. The map position referred to by Applicant encodes hundreds, if not thousands, of gene products, many of which are likely to be expressed in the brain. There is no experimental evidence that the particular protein employed in the claimed assay is associated in any way with schizophrenia. Further, 7q21 is far from the only chromosomal locus believed to be associated with schizophrenia. Table 2 on page 693 of the

Sawa et al. publication (SCIENCE 296:692-695, 26 Apr. 2002) identifies no less that eight chromosomal loci which may be associated with schizophrenia, and that list does not include the locus identified by Applicant. Therefore, one of ordinary skill in the art would not reasonably believe that the evidence of record supports a conclusion that the protein employed in the claimed assay is associated with schizophrenia or is a potential target that is useful in the identification of anti-psychotic drugs.

Even if one believed that a protein of the instant invention corresponded to a protein having a causal association with schizophrenia, it would still not be useful in the claimed assay. The disclosed protein is presumed to correspond to a normal phenotype. The useful form of that protein would be the abnormal gene product found in individuals suffering from schizophrenia and that form of the protein, if it exists, has yet to be discovered. It is a mater of law that the claimed invention must have a practical utility in currently available form. Before the claimed process could be employed in the practical application of identifying compounds with potential anti-psychotic activity, the artisan must first establish a relationship between the protein employed in that process and schizophrenia, and such a relationship would only apply to a form of that protein which has yet to be discovered. Therefore, the claimed process is clearly not useful in its currently available form.

5) Claims 45 to 48 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

6) Claims 46 and 48 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the claimed invention for those reasons of record in section 7 of Paper Number 13. As stated therein these claims require a receptor a "binding partner" and the instant specification fails to identify even a single compound which is capable of binding to the protein described therein. Applicant has traversed this rejection on the premise that the instant specification identifies several classes of compounds known to bind to G protein-coupled receptors and provides the guidance needed to distinguish between a compound which binds to a particular receptor protein from one that doesn't. As stated in the original rejection, because different members of the G protein-coupled receptor family are known to bind to a variety of different, structurally unrelated compounds ranging from simple compounds like glutamate, glycine, dopamine, serotonin, somatostatin, epinephrin, and "odorants" to complex molecules such as interleukin-8 an artisan would have to resort to a substantial amount of undue experimentation consisting of screening essentially every naturally occurring soluble chemical compound present in the human body in order to identify one which is a "binding partner" for a putative receptor protein of the instant invention.

7) Applicant's arguments filed 29 November of 2002 have been fully considered but they are not persuasive.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800